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| 09/998,832 | 11/29/2001 | Robert Chow | 020035-001100US | 7166 |

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EXAMINER

SHUKLA, RAM R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant No.

09/998,832

Applicant(s)

CHOW ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 26 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-6 and 18-26, drawn to a method of preventing or treating HIV infection by screening for stem cells that have a beneficial gene that alters the ability of HIV to infect cells and transplanting said cells into a patient, wherein said beneficial gene encodes SDF-1 alpha, classified in class 424, subclass 93.1.
- II. Claims 1-5, 7 and 18-26, drawn to a method of preventing or treating HIV infection by screening for stem cells that have a beneficial gene that alters the ability of HIV to infect cells and transplanting said cells into a patient, wherein said beneficial gene encodes RANTES, classified in class 424, subclass 93.1.
- III. Claims 1, 2, 8-9 and 18-26, drawn to a method of preventing or treating HIV infection by screening for stem cells that have a beneficial gene that alters the ability of HIV to infect cells and transplanting said cells into a patient, wherein said beneficial gene encodes a HLA complex protein, classified in class 424, subclass 93.1.
- IV. Claims 1, 2, 10-11, and 18-26, drawn to a method of preventing or treating HIV infection by screening for stem cells that have a beneficial gene that alters the ability of HIV to infect cells and transplanting said cells into a patient, wherein said beneficial gene encodes a receptor or coreceptor for HIV entry, wherein said receptor is CD4, classified in class 424, subclass 93.1.

- V. Claims 1, 2, 10, 12-13 and 18-26, drawn to a method of preventing or treating HIV infection by screening for stem cells that have a beneficial gene that alters the ability of HIV to infect cells and transplanting said cells into a patient, wherein said beneficial gene encodes a receptor or coreceptor for HIV entry, wherein said receptor is CCR2, classified in class 424, subclass 93.1.
- VI. Claims 1, 2, 10, 14-17 and 18-26, drawn to a method of preventing or treating HIV infection by screening for stem cells that have a beneficial gene that alters the ability of HIV to infect cells and transplanting said cells into a patient, wherein said beneficial gene encodes a receptor or coreceptor for HIV entry, wherein said receptor is CCR5, classified in class 424, subclass 93.1.

3. Claims 1-2 link inventions of the groups I-VI. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 1-2. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 USC 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129,131-132 (CCPA 1971). See also MPEP 804.01.

4. Claims 1-5 link inventions of the groups I-II. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 1-5. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s)

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depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 USC 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129,131-132 (CCPA 1971). See also MPEP 804.01.

5. Claim 10 links inventions of the groups IV-VI. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claim 10. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 USC 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129,131-132 (CCPA 1971). See also MPEP 804.01.

6. Claims 18-26 are common to the groups I-IV. These claims will be examined to the extent they encompass the elected invention.

7. Inventions of the groups I-VI are patentably distinct each from the other because they are drawn to methods of treatment using stem cells that express different genes which have very divergent structure and function. For example, the structure of a ligand for HIV entry, such as SDF-1 alpha will be distinct from that of

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RANTES. Likewise the structure of HLA complex proteins will be different from those of the ligands of HIV receptors or the receptors themselves. Therefore, search for a ligand or receptor or HLA complex protein will not be coextensive and will require separate and independent searches in the patent and non-patent literature. It is noted that while all the invention are grouped in the same class/subclass because they are drawn to a method of treatment using cells, they are patentable distinct for reasons discussed above.

8. Claim 9 is generic to a plurality of disclosed patentably distinct species comprising MHC class I, MHC class II, TNF and complement. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Claim 18 is generic to a plurality of disclosed patentably distinct species comprising embryos, marrow, peripheral blood, placental blood, umbilical cord blood and adipose tissue. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632